

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates scientific information on effects that may result from exposure to environmental contaminants. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. Sound science is the cornerstone of EPA's efforts to protect human health and the environment.

- In June 2010, EPA decided to put four of its ongoing IRIS assessments on hold pending a review of some of the underlying studies used in the assessments. EPA made this decision after receiving a report from the National Toxicology Program (NTP) that reviewed results of some research studies completed by the Ramazzini Institute, a lab in Italy that conducts animal testing to evaluate the potential cancer-causing effects of chemicals. The report found differences of opinion between NTP scientists and the Ramazzini Institute (RI) in the diagnosis of certain cancers reported in a study on methanol.
- To follow up on these findings, EPA collaborated with the National Institute of Environmental Health Sciences (NIEHS) to jointly sponsor an independent group of scientists, the Pathology Working Group (PWG), to review a larger group of animal studies performed in the Ramazzini lab.
- PWG scientists found fewer numbers of leukemias and lymphomas than had been originally reported by the Ramazzini Institute. The report pointed out some instances where the presence of respiratory infections in RI study animals made definitive diagnoses difficult, and that some RI diagnoses, primarily certain leukemias and lymphomas, were not considered to be malignant tumors.
- Because of the differences of opinion between the RI and PWG scientists in diagnosing leukemias and lymphomas, EPA has decided not to rely on data from the RI on lymphomas and leukemias in IRIS assessments. This decision will impact IRIS assessments under development for methanol, MTBE and ETBE. The draft assessment for acrylonitrile is not affected, as EPA relied on data from sources other than the Ramazzini Institute to complete the draft assessment.
- There was good agreement between the RI and PWG scientists in diagnosing solid tumors such as liver tumors from the RI study on vinyl chloride. EPA has therefore decided to continue to use RI solid tumor data in IRIS assessments. RI solid tumor findings will be reviewed along with other data in determining the overall weight of evidence of carcinogenicity for substances on which EPA is conducting IRIS assessments.
- The PWG made recommendations for changes in RI's laboratory procedures and EPA hopes that RI will fully implement these recommendations to allow for the use of future RI data in IRIS assessments.